DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

STATEMENT OF

BERNADETTE M. DUNHAM, D.V.M., PH.D.

DIRECTOR

CENTER FOR VETERINARY MEDICINE

FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

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COMMITTEE ON ENERGY AND COMMERCE

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INTRODUCTION

Good morning, Chairman Pallone and Members of the Subcommittee. I am Dr. Bernadette Dunham, Director of the Center for Veterinary Medicine (CVM) at the U.S. Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services (HHS). I am accompanied today by Dr. Steven Vaughn, Director of CVM's Office of New Animal Drug Evaluation, and Mr. David Wardrop, Jr., Executive Officer and Director of CVM's Office of Management. FDA appreciates the opportunity to testify on the reauthorization of the Animal Drug User Fee Act (AGDUFA) and the proposed Animal Generic Drug User Fee Act (AGDUFA).

I'd like to begin my testimony today by speaking about the reauthorization of ADUFA, including a description of ADUFA's performance to date and a description of how FDA's recommended improvements for ADUFA II fulfill the goals set by the House Committee on Energy and Commerce, the Senate Health, Education, Labor and Pensions Committee, FDA and others. I will then briefly describe the proposed AGDUFA.

ADUFA

BACKGROUND

As authorized by Congress and signed into law in 2003, ADUFA amended the Federal Food, Drug, and Cosmetic Act to authorize FDA to collect user fees from the animal drug industry to enhance the process for the review of animal drug applications. The goal of ADUFA is to better serve public and animal health by providing additional funds to

augment FDA resources dedicated to the application review process. Shorter, more predictable review times are achieved by increasing the review staff at CVM and building better management systems. Fees collected under ADUFA are in addition to base appropriations and enable FDA to pursue a comprehensive set of review performance goals and commitments designed to improve the timeliness and predictability of the review of new animal drug applications (NADAs), supplemental NADAs, and investigational new animal drug (INAD) submissions.

Under ADUFA, FDA committed to meeting the performance goals specified in letters from the Secretary of Health and Human Services to the Chairmen of the House Committee on Energy and Commerce and the Senate Committee on Health, Education, Labor, and Pensions.

ADUFA ACHIEVEMENTS

I'm here today to report to Members of the Subcommittee some very good news. Since the enactment of ADUFA, FDA has exceeded all of the review performance goals established under ADUFA. The performance goals under ADUFA were intended to achieve progressive, yearly improvements in the process for review of NADA's. FDA agreed to review and act on submissions within shorter periods of time each successive year. For example, review times for original NADA's have decreased from 295 days to 180 days. This has been accomplished by hiring additional FDA staff; providing training and educational opportunities for FDA animal drug review staff; developing and disseminating guidance, policy, and procedural documents; and implementing business

process improvements. These actions are an integral part of FDA's commitment to improving the efficiency, quality, and predictability of the new animal drug review process. The best news is that resources provided by ADUFA have allowed CVM scientists to keep pace with the rapid advances in science and medicine that drive the quality of health care as part of their work in reviewing animal drug applications. User fee funding also enables us to hire and retain highly qualified scientific staff to address critical public health issues, such as antimicrobial resistance, that play a role in the review of NADAs.

As the Prescription Drug User Fee Act (PDUFA) enhanced the review of human drugs, so has ADUFA benefited the review of animal drugs. This legislation has been extremely valuable in helping FDA fulfill our commitment to promote and protect public and animal health.

REAUTHORIZATION

The user fee provisions of ADUFA will sunset on October 1, 2008, if not reauthorized. Timely reauthorization is needed to ensure there is no disruption to this program. In preparing our proposed recommendations for ADUFA reauthorization, we held a public meeting on April 24, 2007. We then negotiated, from May through August 2007, with the Animal Health Institute, which represents the majority of the animal drug industry for pioneer drugs. FDA then published the negotiated recommendations in the *Federal Register* on February 21, 2008, held a public meeting for comments on those recommendations on March 11, 2008, and provided a 30-day comment period on the

same (that comment period closed April 14, 2008). The proposal FDA presented to Congress on April 24, 2008, included input from our stakeholders.

PROPOSAL FOR ADUFA II

Our goals for the legislative proposal to reauthorize ADUFA are to sustain and enhance the core program's operation and performance while providing predictable review times and resources sufficient to keep pace with actual costs.

Recommendations presented in the proposal to accomplish these goals fall into two categories:

A. Enhancements to performance provisions; and
B. Enhancements to program funding.

I'd like to describe those recommendations in a bit more detail.

A. Enhancements to performance provisions

FDA's proposal includes several performance-improving enhancements aimed at reducing costs for some submissions, providing for improved handling of inspections, improving communication between sponsors and the Agency, and increasing the flexibility of the application process.

First, a new End-Review Amendment process has been developed in an attempt to reduce review cycles. Under ADUFA I, in cases of an incomplete application, FDA must issue an "incomplete" letter for the application. The sponsor must then correct and resubmit the application, at which time a new review cycle starts. This adds considerable time and expense to those application reviews. Under ADUFA II, for applications that are nearly

satisfactory but need non-substantial changes, a new "End-Review Amendment" process will allow sponsors to provide an amendment within a specified timeframe, allowing the Agency to immediately review the amendment and approve the application, if appropriate, without starting a new review cycle. This change will significantly reduce costs and expenses associated with second reviews.

Another enhancement to the process for reviewing animal drug applications is the creation of a process allowing for the voluntary submission by sponsors of a list of foreign manufacturing facilities that may be subject to a premarket approval inspection during the fiscal year. In addition, a sponsor may notify FDA 30 days prior to submitting an animal drug application, supplemental animal drug application, or investigational animal drug submission that it includes a foreign facility. This change will allow FDA to better predict and organize pre-approval inspections.

In addition, FDA is recommending a number of changes to improve communication between the Agency and sponsors to increase the efficiency of the application submission process. FDA and regulated industry have agreed to participate in ten public workshops by the end of Fiscal Year (FY) 2013 on mutually agreed upon topics. FDA will explore and discuss the applicable use of pharmacokinetic/pharmacodynamic data and will explore opportunities for exchange of information regarding the characteristics of new animal drugs. FDA will use both formal meetings and informal communication with stakeholders to ensure complete submissions.

Finally, FDA will develop an electronic submission tool for industry submissions, thereby allowing online review capability of applications by FDA.

Beyond the stated goals, FDA's proposal includes technical changes to increase the administrative efficiency of the user fee program. These changes are designed to clarify several ADUFA definitions and to remove potential ambiguity. FDA's analysis of the impact of these changes indicates that they would be revenue-neutral and would have a minimal impact on industry.

FDA believes this agreement will continue the sustained performance improvements established by ADUFA, enhance communications between FDA and regulated industry, enable FDA to maintain high standards of safety and effectiveness of animal drugs, and provide revenue for sustained performance while maintaining our critical public health mission.

B. Enhancements to program funding provisions

Although user fees have provided important resources to FDA since the beginning of the program, user fees have not kept up with the increasing costs of the program associated with inflation in pay and benefit costs to the Agency and rent and rent-related costs. FDA is proposing changes to the financial provisions of ADUFA to address these shortcomings and place the program on sound financial footing so FDA can continue with the program and enhance it. The proposed funding level is $98 million over five years.

Based on an analysis of FDA's recent costs history and anticipated costs over the next five years, FDA expects the trend of increasing costs to continue. FDA's proposed recommendation to Congress, after consultation with regulated industry, is that the total fee revenue estimate for each of the five fiscal years of ADUFA II be the amounts set out in the table below:

Fiscal Year	2009	2010	2011	2012	2013	Total
Total Revenue Target	$15,260,000	17,280,000	$19,448.000	$21,768,000	$24,244,000	98,000,000

With the level of funding proposed, FDA has confidence that it will have a stable review workforce over the five years to be covered by ADUFA II**.** That assurance of a stable animal drug review workforce enables FDA to commit to a continuation of the FY 2008 performance goals throughout the period covered by ADUFA II as well as to additional performance enhancements.

AGDUFA

Currently, FDA's review of generic animal drugs is funded entirely through appropriations. Under FDA's generic animal drug user fee proposal, the generic animal drug industry would pay user fees that would be available to FDA, in addition to appropriated funds, to spend on the process for the review of generic animal drug submissions. The proposed legislation will generate an estimated $27 million in user fees over five years. Fees dedicated to the review process of such applications will

provide essential resources to improve generic animal drug review times. Despite several management initiatives already implemented to make this review process more efficient, there has been a significant increase in review times for generic animal drug submissions. At the end of FY 2007, there was a backlog of 446 submissions for generic animal drugs. That's an increase of 93 percent over the FY 2000 number. The statutory review time frame for ANADAs is 180 days. In FY 2007, the actual review time averaged 570 days. With 49 pioneer animal drugs due to come off patent between 2009 and 2011, review times are certain to increase unless improvements are made. This legislation is critical to FDA improving its approval process for generic animal drugs.

By passing AGDUFA, Congress will provide significant savings to ranchers, farmers, rural communities, and pet owners who struggle to pay the high price of pioneer drugs for their animals. This legislation will provide a 75 percent cost savings to the end user for a food-producing animal drug and a 30 percent cost savings to pet owners for companion animal drugs.

FDA recognizes the great need for improved response times for generic animal drug applications. From September through November 2007, in response to that need, the Agency held negotiations with the Generic Animal Drug Alliance, which represents the majority of the animal generic drug industry. From input gained through those negotiations, FDA formulated recommendations for a generic animal drug user fee program and presented those recommendations to Congress on April 24, 2008.

Similar to the Agency's ADUFA proposal, FDA's AGDUFA recommendations ensure

that the generic animal drug user fee program will have a sound financial footing and strong performance goals. Resources generated through user fees will be sufficient to cover the actual costs of meeting specified performance goals. Revenues generated by the AGDUFA proposal increase annually from $4.8 million to $6 million over five years for a total of $27 million. As with ADUFA, revenue amounts from fees account for yearly cost of inflation, so no further inflation adjustment is necessary.

The AGDUFA fee structure uses three streams to generate revenue – application fees, sponsor fees, and product fees. Sponsor fees are graduated based on the number of approved applications a sponsor holds. In addition, there is a waiver for Minor Use and Minor Species applications/submissions as there is in ADUFA.

FDA's AGDUFA proposal includes an adjustment mechanism for potential sustained increases in workload. The program delays offset collections to the final year and utilizes the same triggers as ADUFA (i.e., Agency level appropriation combined with review process level appropriation).

AGDUFA's performance goals also mirror those of ADUFA. The first of those goals is the reduction of specific review times for sentinel submissions over five years. As an example, it is estimated that the review of an original ANADA that will take approximately 700 days in FY 2009 will take 270 days in FY 2013. For generic investigational new animal drugs (JINAD) protocols, the 400 days needed to review in 2009 will be reduced to 100 days by 2013. These are considerable improvements in the

approval process, and they will go a long way in bolstering a struggling generic animal drug industry.

The AGDUFA proposal also includes an amendment process to reduce the time and review cycles associated with multiple submissions from a sponsor that are similar to one another. This provision is to be implemented no later than FY 2012. Under this provision, in most cases, if FDA requests an amendment to an animal drug application/submission, or if the Agency issues an incomplete letter for such an application/submission, a sponsor may request to amend other, similar applications or submissions. This will reduce the time and review cycles associated with any related submissions from a sponsor.

Again, like ADUFA, AGDUFA includes various changes aimed at improving communication between sponsors and the Agency.

Resources generated by AGDUFA will be used to increase review staff, refine FDA's business process for review of generic animal drug submissions, provide training and development for program staff and develop policies targeted at more efficient review. This proposal benefits from lessons learned through ADUFA and, with it, FDA will continue to maintain high standards of safety and effectiveness for animal drugs and provide sustained revenue for improved FDA review performance.

CONCLUSION

FDA's ADUFA and AGDUFA legislative proposals represent considerable input from and agreement of stakeholders, the public, and the Agency. They represent methods by which FDA will improve its pioneer animal drug user fee program and institute the first generic animal drug user fee program. FDA urges passage of these proposals, and we will work with Congress in any way we can to assist with that effort.

Thank you for the opportunity to present testimony before the Subcommittee. I would be happy to answer any questions.